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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,776	08/28/2003	Ralph M. Ellison	077319-0389	5848
22428	7590	12/15/2005	EXAMINER	
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			PAK, JOHN D	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/649,776	Applicant(s) ELLISON ET AL.	
	Examiner JOHN PAK	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/04, 10/04</u> . | 6) <input type="checkbox"/> Other: ____ |

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Claims 1-11 are pending in this application.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over CN 1079391 in view of Zhang (US 6,720,011) and Shimotsuura et al.

CN 1079391 discloses the use of highly pure trivalent arsenic oxide in combination with traditional Chinese medicine to treat cancer (English translation of claim 1 & translation page 7, first full paragraph). Treatment of body surface tumor with arsenic trioxide is taught (translation page 7, first full paragraph). Treatment of skin cancer with white arsenic paste or arsenic trioxide is already known (Translation page 6, lines 13-20). Paste and injection formulation of arsenic trioxide for body surface tumors are taught (paragraph bridging pages 7-8 of the translation; see also translation page 12, last paragraph).

Zhang discloses treating various cancers with arsenic trioxide. See column 1, lines 4-6, 33-35 and 41-43. Intravenous composition containing 1-10 g arsenic trioxide, sodium chloride and water (column 1, lines 41-54). "[S]trong

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abruptive effect on the membranes of cancer cells” is disclosed, as well as inhibition of DNA/RNA synthesis (column 1, lines 58-61). Effective daily dose for an adult is disclosed as 10 ml of the composition containing 10 g/l arsenic trioxide added to 500 ml of 10% glucose solution is disclosed. This calculates to about 67 mg/day. Appropriate dose is to be “decreased accordingly for children” (column 2, lines 9-16).

Shimotsuura et al. disclose that antineoplastic actions of arsenic trioxide are primarily achieved by DNA composition blockage (page 25 of the English translation, top of page 49 in the original).

CN 1079391 does not **explicitly** disclose treating **melanoma** in a human by administering arsenic, either alone or in combination with other chemotherapeutic or radiotherapeutic agents. However, for the reasons to follow, the claimed invention as a whole would nonetheless have been obvious to the ordinary skilled artisan in this field at the time the invention was made.

CN 1079391 teaches efficacy of arsenic against skin cancer and body surface tumors. Although “melanoma” is not expressly disclosed in verbatim language, it would have been suggested from the disclosure of CN 1079391 because melanoma is a malignant skin cancer. Further, Zhang broadly teaches efficacy of arsenic trioxide against cancers and a strong abruptive effect on the membranes of cancer cells and inhibition of DNA/RNA synthesis. Taken with

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teachings of Shimotsuura et al., which confirm the DNA composition blockage action of arsenic trioxide antineoplastic, the ordinary skilled artisan in this field would have been motivated to administer arsenic trioxide to treat patients with melanoma, as claimed. Because melanoma is an uncontrolled growth of cells, one having ordinary skill in the art would have been motivated to administer arsenic trioxide to treat such uncontrolled growth of cells, particularly in view of its adverse effect on rapid DNA replication.

Applicant's dependent claim feature of ionic aqueous solution is noted. Ionic aqueous solution is suggested by the various ions in CN 1079391 (translation of claim 5) and the sodium chloride present in Zhang's arsenic trioxide solution (column 1, lines 44-45).

Varying the dose according to the body weight of a human (applicant's claim 11) is suggested by Zhang's teaching of appropriately decreasing the dose for children.

IV administration is suggested by the injection formulation of CN 1079391 and explicit IV injection teaching of Zhang.

As for combined use with radiation or other chemotherapeutic agents, such method would have been fairly suggested from the conventional practice in the cancer treatment field to combine the actions and benefits of several therapies to attack the cancer cells from a variety of mechanisms. The

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therapeutic agents listed in claim 10 are all well-known anti-cancer agents and inclusion of such additional anti-cancer agents in combination with arsenic trioxide would have been fairly suggested.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly suggested by the teachings of the cited references.

For these reasons, all claims must be rejected.

Applicant is advised that several references listed on PTO-1449 were crossed out due to their (i) re-listing as the published documents, (ii) non-English language disclosure, or (iii) duplicate listings. Of the documents that are not crossed out, several are not in the English language. The record should reflect the fact that such references are indicated as being considered (initialed) solely to the extent that the Examiner, who is not familiar with the French, German, Chinese and Japanese languages, could make out a cursory understanding of the disclosed topics therein. In this regard, applicant should note that only a search report from a **counterpart** foreign application can serve as a substitute for English language explanation of a document's relevance. To date, applicant

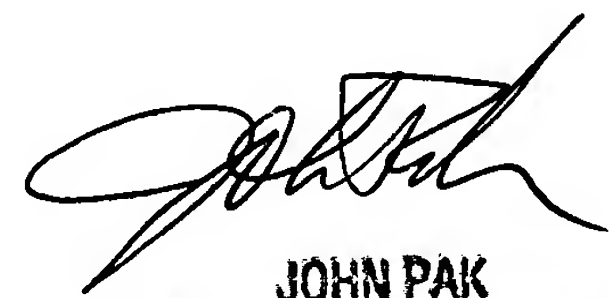
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has not clarified which of the many search reports cited in the PTO-1449 is for the counterpart foreign application to the instant application.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machines is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner John Pak whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Mr. Gary Kunz, can be reached on **(571)272-0887**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is **(571) 272-1600**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have a question on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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